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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,769	11/10/2003	Mary Beth Watkins	1200375.1001	7859

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,769	WATKINS ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending in the application and were examined on their merits.

Specification

The use of the trademark Nico-Rx has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6, 7, 10, 13, 19 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, the claimed invention lacks

patentable utility and because the disclosed invention is inoperative and therefore lacks utility.

In the Instant case, Applicant has claimed amounts of plant material that are unobtainable and/or inoperable. For example, although Applicant has not explained in the Specification what the concentrations '4X, 6X, 12X and 30X' mean, it is known that in homeopathic concentrations, 1/10 =1X, that is, 1X is a 1:10 dilution. Similarly, 4X is a1/10,000 dilution, 6X is a 1/1,000,000, 12X is a 1/1,000,000,000,000 dilution and 30X is a1/1,000,000,000,000,000,000,000,000,000,000.

It is deemed that concentrations of this nature would fail to provide any therapeutic effect especially absent evidence to the contrary. Further, it is deemed that the concentration '30X' is an impossible concentration, which goes beyond the knowledge of scientific principals. It is deemed that, in a '30X' concentration, that not even one molecule will be present since, according to Avogadro's number, one molecule is present in 10^{24} (parts).

Because these claims fail to lack utility, they also fail to provide for the provisions set forth under 35 USC 112 First paragraph, which will be discussed keenly *infra.*

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, with regard to claims 1-7, claims 4 and 6 limit claim 1 to certain herbals which may be incorporated as the 'first homeopathic composition', and claims 5 and 7 limit claim 1 to certain herbals which fit the description of the 'second homeopathic composition'. However, none of these claims limit both the 'first homeopathic composition' and the 'second homeopathic composition' to actual herbals as taught in the Instant Specification. It is deemed that with regard to the 'homeopathic composition' itself, aside from the Written Description rejection placed on these claims as a whole because it is deemed that Applicant's were not in possession of the concentrations claimed as 'a pharmaceutically effective amount' (which will be more keenly discussed

infra), Applicant does not disclose a reasonable number of 'homeopathic compositions' in order to verify that Applicant was in possession of such a possibly infinite amount of compositions. The Instant Specification does not define 'homeopathic composition'. Webster's dictionary defines 'homeopathy' in part as: a system of medical practice that treats a disease especially by the administration of minute doses of a remedy that would in healthy persons produce symptoms similar to those of the disease. Thus, Applicant is attempting to claim every remedy, including every known and undiscovered drug, plant and plant extracts. It is deemed that Applicant was not in possession of such an enormous permutation of possible 'remedies'.

It is further deemed that Applicant was not in possession of an 'effective amount' of any of the plants as listed in claims 4 and 5 or 8 for example. It is deemed that amounts such as 4X, 6X, 12X and 30X are not proven effective amounts for treatment of nicotine cessation . Further, it is noted that the claims state plant material which has been diluted, therefore, in essence, what Applicant is claiming is an aqueous (or other type of solvent) extract of these plants, and not the plant matter itself. It is deemed that it is *a priori* unpredictable to ascertain if any one molecule of plant material will be present in these dilutions, and if one molecule is present, what that molecule will be. For example, in a 6X dilution of Plantago major for example, the plant is diluted 1,000,000 times. In one dose of Plantago major, one dose (wherein the dosage has not been defined in the Instant specification as discussed *infra*) theoretically one milliliter, there is a slight chance that *one molecule* of the original plant material will be present,

wherein the plant contains a vast amount of endogenous material such as proteins and phytochemicals, *inter alia*. That molecule may be an amino acid for example.

Therefore, Applicant may have been in possession of an amino acid, but the Examiner cannot be sure since any sample taken from this dilution would need to be tested in order to ascertain if any molecules are present at all.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Because the claims lack utility, and fail to show that Applicant was in possession of the invention, it is deemed that the skilled artisan could not make or use the compositions/methods as Instantly claimed.

The instant specification fails to teach how to make the composition, in that the amounts of starting material and extraction solvents are not disclosed, nor is the method for serial dilutions in order to arrive at such large dilutions discussed. Further, the Specification does not teach what doses would be effective. There is not even one actual or even theoretical example where the composition as claimed was useful for

treating nicotine cessation or any other ailment/disease.

The unpredictability with regard to large dilutions of plant extracts is well documented in the literature. No scientific data supported by empirical evidence is found in the Instant specification nor in the prior art to substantiate the claimed effectively of the compositions toward nicotine cessation or any other ailment/disease.

Thus, the skilled artisan would not have any reasonable expectation for success in producing or using the invention as claimed without undue experimentation.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Thursday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1655

9/5/05